

*REMARKS*

Reconsideration of the pending application is respectfully requested in view of the following remarks.

*Discussion of the New Claims*

Claims 1-64 were previously submitted and are currently under examination, with claims 65-67 being canceled, without prejudice, and claims 68-70 being new. As the amendments to the application are fully supported by the application as filed, no new matter has been introduced into the application by way of these amendments.

*Summary of the Office Action*

Claims 1-17, 28-41 and 52-54 are provisionally rejected for alleged obviousness-type double patenting over claims 1-47 of copending U.S. Patent Application No. 10/434,776.

Claims 1 and 3-67 are rejected under 35 U.S.C. § 102(b) as allegedly unpatentable over U.S. Patent 6,399,087 ("Zhang et al.").

*Discussion of the Claim Rejections*

With regard to the obviousness-type double patenting rejection, Applicants may file a terminal disclaimer addressing this rejection upon receipt of an indication of allowable subject matter.

With regard to the rejection under 35 U.S.C. § 102(b), Applicants respectfully traverse the anticipation rejection.

The Office Action alleges that Zhang et al. teaches compositions containing propofol with the other ingredients and in concentration ranges claimed in the current application. What is not alleged in the Office Action, however, is any disclosure or teaching in Zhang et al. relating to the use of any container for its compositions, let alone the use of a container which comprises a closure that is inert to propofol. In contrast to the assertion in the Office Action, the invention as described in independent claims 1, 29 and 52 provides a sterile pharmaceutical composition of propofol in a container, and comprises both a container and a composition in the container. In claim 1, for example, the container includes a closure and the composition in the container comprises propofol and less than about 10% by weight solvent for propofol, wherein the closure is inert to propofol. One advantage provided by the

claimed invention is a lessening of degradation and potency of propofol relative to prior art propofol packaged products. A container, and indeed one having a closure that is inert to propofol, is clearly a substantive limitation of the invention as claimed.

The Office Action asserts that Zhang et al. discloses each and every claim limitation. However, this argument ignores certain claim limitations relating to the container, and in particular the “wherein” clause. In this regard, the Office Action argues that “how the propofol is stored is not relevant to the instant invention” because it does not modify the pharmaceutical composition. *See* Office Action, pages 5-6.

Applicants respectfully submit that the container limitation is within the body of the claim, and must be considered as a substantive limitation. When the claims are considered in this manner, there is no question that the claims are patentable over Zhang et al.

Applicants note that it is not argued in the Office Action, nor could it be, that Zhang et al. discloses or teaches the claimed invention as a whole which includes both container and composition therein. More specifically, and in the case of illustrative claim 1, the invention provides a sterile pharmaceutical composition of propofol in a container, comprising a container which includes a closure and a composition in the container, the composition in the container comprising propofol and less than about 10% by weight solvent for propofol, wherein the closure is inert to propofol. Zhang et al. fails to disclose or teach the claimed combination of container and composition.

The Office Action relies on *Hoffer* in support of its argument that the “wherein” clause of claim 1 expresses merely the intended result of a process or method. *See* Office Action pages 5-6. The *Hoffer* court, however, was construing a “whereby” clause in a method claim (as opposed to a “wherein” clause), and the holding was restricted to those claims in which a “whereby” clause expresses the “intended result” of the process or method, but is not necessarily a part of the process or method itself. *See Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005).

Reliance on the *Hoffer* case is misplaced. First, the claims under consideration here do not include a “whereby” clause at all, but a “wherein” clause. Second, the recitation of the closure in Applicants’ “wherein” clause is in no way an “intended result” of a process or method but is, in fact, a part of the invention itself. The Federal Circuit has stated that “wherein” clauses are limitations when “they relate back to and clarify what is required” by

the claim. *See Griffin v. Bertina*, 62 USPQ2d 1431, 1434 (Fed. Cir. 1997). In *Griffin*, the Federal Circuit noted that the “wherein” clause in issue “expresses the inventive discovery of the correlation between” a certain genetic mutation and disease resistance, and was therefore a limitation as it related back to and clarified what was required of the count. *Id.* In a similar way, and referring again to claim 1, Applicants’ “wherein” clause relates back to and clarifies what is required in claim 1, namely that the propofol container’s closure must be inert to propofol. Thus, the “wherein” clause recited in the pending claims is, without doubt, a substantive limitation under Federal Circuit law, *e.g.*, *Griffin*.

As Zhang et al. fails to disclose or suggest the invention as recited in independent claims 1, 29 and 52, *e.g.*, a sterile pharmaceutical composition of propofol in a container, comprising a container which includes a closure and a composition in the container, the composition in the container comprising propofol and less than about 10% by weight solvent for propofol, wherein the closure is inert to propofol (claim 1), Applicants respectfully request that the rejection be withdrawn.

#### *Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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